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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,853	08/26/2002	Frank Cuttitta	2026-4316US1	2579

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KLARQUIST SPARKMAN, LLP
121 S.W. SALMON STREET, SUITE #1600
ONE WORLD TRADE CENTER
PORTLAND, OR 97204-2988

EXAMINER

COOK, LISA V

ART UNIT PAPER NUMBER

1641

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,853

Applicant(s)

CUTTITTA ET AL.

Examiner

Lisa V. Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Supplemental Restriction Requirement

1. Attorney Hardin phoned examiner Cook regarding the restriction requirement mailed 9/7/05. A typographical error occurred in the restriction requirement. The office action summary was directed to the correct application and claims, however the body of the restriction was drawn to another set of claims. Accordingly a new office action was sent out to replace the erroneous mailing on 9/7/05. Examiner Apologizes for any inconvenience this may have caused Applicant.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature that appears to link claims 1-52 is the binding complex formed between adrenomedullin(AM) and AM binding peptides like factor H. However the reference of Martinez et al. (Endocrinology, Vol.138, No.12, 1997, pages 5597-5604). Therefore the technical feature recited in claims 1-52 is not a contribution over the prior art. Accordingly the groups set forth below are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

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- A. Group I, claim(s) 1-5 are drawn to a method of measuring adrenomedullin levels in a sample via sample addition with a chaotropic agent to *dissociate* adrenomedullin/factor H, fractioning, and quantification of adrenomedullin (A 1st first method employing a special technical feature or chaotropic agent).
- B. Group II, claim(s) 6-16 are drawn to a method of measuring a complex (*association*) formed between factor H and adrenomedullin in a subject with a condition (A 2nd method that utilizes a special technical feature).
- C. Group III, claim(s) 17-20 and 37-40 are drawn to kits comprising factor H or adrenomedullin peptide binding fragment (such as an antibody). (A 1st product comprising a special technical feature).
- D. Group IV, claim(s) 21, 22, and 23 are drawn to methods of identifying antagonist agents that inhibit factor H/adrenomedullin complex formation as well as the pharmaceutical composition. (A 3rd process of identifying a special technical feature and the composition identified).
- E. Group V, claim(s) 24 and 25 are drawn to a method of inhibiting growth or proliferation of cancer or tumor cells utilizing an antagonist agent. (A 4th process utilizing the special technical feature or antagonist).
- F. Group VI, claim(s) 26-36 are drawn to an isolated and purified protein complex comprising adrenomedullin and factor H, antibodies specific thereto, compositions comprising the complex, and methods of isolating and detecting said complex. (A special technical feature, methods of isolating and detection the special technical feature).

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- G. Group **VII**, claim(s) 41-44 are drawn to a method of inhibiting growth or proliferation of cancer or tumor cells via the administration of antibodies reactive with the complex formed between adrenomedullin and factor H or a fragment thereof. (Another method using a special technical feature).
- H. Group **VIII**, claim(s) 45-50 are drawn to a method of treating a condition associated with decrease secretion of insulin by pancreatic cells employing an antagonist. (Another method using a special technical feature).
- I. Group **IX**, claim(s) 51-52 are drawn to a method of treating a condition associated with an autoimmune response to pancreatic cells via the administration of factor H. (Another method using a special technical feature).

3. The inventions listed as Groups A through I do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Under PCT rules Applicant is entitled to an examination of one of the combination groupings: (1) a product, a method of using said product and a method of producing said product. The instant claims are directed to multiple methods, products, and special technical features, therein applicant must select one for further prosecution.

4. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

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Because these inventions are distinct for the reasons given above and the search required for Group A through I are not totally inclusive, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO fax center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lisa V. Cook
Patent Examiner
Remsen 3C-59
(571) 272-0816
11/2/05



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

11/10/05